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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,313	07/15/2005	David J. Rys	1282-P02956US01	6431

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EXAMINER	
PURDY, KYLE A	

ART UNIT	PAPER NUMBER
4173	

MAIL DATE	DELIVERY MODE
11/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,313	RYS ET AL.	
	Examiner	Art Unit	
	Kyle A. Purdy	4173	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) 5-10 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-4 and 11-23 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 2 Sheets.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election Acknowledged

1. Applicants' election without traverse the invention of Group I encompassing claims 1-23 filed on October 08, 2007 is acknowledged. The restriction was made without traverse. Therefore, the restriction requirement is deemed to be proper and made final.

Status of Application

2. Claims 5-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 08, 2007.

3. Thus claims, 1-4 and 11-23 are examined on the merits. The following rejections are made.

Double Patenting

4. Applicant is advised that should claim 2 be found allowable, claim 3 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 11-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating pneumovirus infections, does not reasonably provide enablement for preventing pneumovirus infections. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

7. There are several guidelines when determining if the specification of an application allows the skilled artisan to practice the invention without undue experimentation. The factors to be considered in determining what constitutes undue experimentation were affirmed by the court *In re Wands* (8 USPQ2d 1400 (FACF 1986)). These factors are the quantity of experimentation; the amount of direction or guidance presented in the specification; the presence or absence of working examples; the nature of the invention; the sate of the prior art; the level of skill of those in the art; predictability or unpredictability of the art; and the breadth of the claims.

8. The instant claims are drawn to a pharmaceutical composition with the intended use of treating and preventing pneumovirus infection, wherein the composition comprises an effective amount of the antiviral to attenuate infectivity of pneumovirus.

9. The skilled artesian would view the prevention of pneumovirus as complicated and highly unpredictable. Based on the specification, it appears that the Applicants are asserting that their claimed compound can act as a preventive agent because the compound is capable of inhibiting pneumovirus replication. However, the applicants have not provided any competent evidence indicating that the composition is preventative as currently embraced by the claim

language. The scope of the claims includes not only treatment but also 'prevention of pneumovirus', the prevention aspect is not enabled on the ground that the active compounds act as effective inhibitors of pneumovirus replication. Furthermore, Applicant has not set forth in the specification how one is defining "prevention of pneumovirus infection". The standard definition of the term prevent as set forth by dictionary.com is applied. The term 'prevent' means to keep form ever happening or impede. Hence, a skilled practitioner in the art would recognize that the prevention of a viral infection such that the subject will never experience any characteristics associated with a pneumovirus infection. As Applicants have not provided any competent evidence or disclosed tests that are highly predictive for the pharmaceutical efficacy for the preventive effect using the instant compounds, the claims are not properly enabled. Importantly, there are no working examples present to sufficiently guide one to prevent a pneumovirus infection. Hence, the lack of guidance in the specification, the absence of data indicating that the compound is a preventive of pneumovirus infections, Applicant is not enabled for the prevention of pneumovirus infection.

10. Therefore, in view of the Wands factors, i.e. the amount of guidance present and absence of working examples as discussed above, to practice the claimed invention herein, a person skilled in the art would have to engage in undue experimentation, with no assurance of success.

Claim Rejections - 35 USC § 103

11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

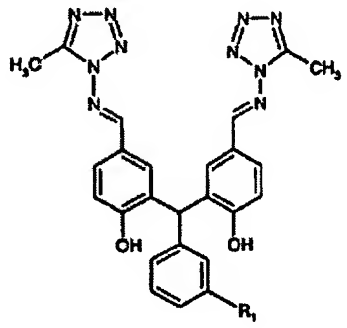
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. **Claims 1-4 and 11-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nitz et al. (WO 99/33508) in view of DeLuca et al. (Pharma. Dosage Forms Vol. 1: Parenteral Medications, 1992, 173-175).**

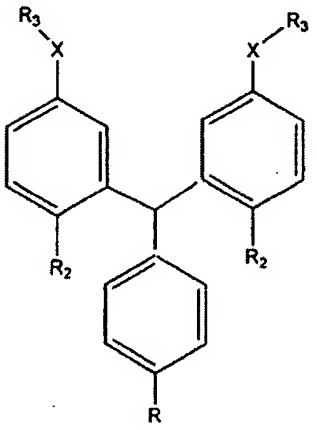
14. The claims of the instant application are drawn to a compound having the following structure



wherein the species occupying the R_1 position is propyl. The compound is used in a pharmaceutical composition, in an amount effective to attenuate infectivity of pneumovirus. The composition further comprises at least one supplemental active agent such as interferons, immunoglobins, antibiotics, etc. The composition may comprise ethanol from 50% to 90% of

the composition, propylene glycol, and water. Preferably however, the composition comprises 85% ethanol, about 10% propylene glycol and less than 5% water.

15. The teaching of Nitz et al. ('508) is drawn to compounds, compositions and methods for treating or preventing pneumovirus infection and associated diseases. The compounds use to treat pneumovirus have the following structure



The species which may occupy the X, R, R_2 and R_3 are identical to those of the instant application in that X may be –C=N, R may be propyl, R_2 is hydroxyl, and R_3 is 5-methyl-1-tetrazolyl (see page 4, line 15 - page 5, line 5 and Example 10). The difference between '508 and the instant application, R and R_1 respectively, is the position of the substituent on the benzene ring. The substituent of '508 is in the para position whereas the instant applications substituent is in the meta position. Typically structural homologs, either isomers (i.e. cix vs. trans) or positional isomers (i.e. meta vs. para), often have similar pharmacological properties. With that stated, chemists of ordinary skill would contemplate making slight variations of a known compound in order to obtain compounds with better and improved properties. The compounds of the prior art would motivate such routine organic synthesis and optimization, leading to the instantly claimed compounds which possess efficacy as inhibitors of pneumovirus

replication. See *In re Deuel*, 51 F.3d 1552, 1558, 34 USPQ2d 1210, 1214. The teaching of '508 also stipulates for the inclusion of supplemental active agents such as interferons, antibiotics, and immunoglobins.

16. The reference teaches that the carrier solvent of the pharmaceutically active compound can consist of any "pharmaceutically acceptable carrier medium" meaning that the carrier includes any and all solvents. This would necessarily encompass and motivate the inclusion of ethanol, propylene glycol and water. Still, however, '508 specifically fails to include ethanol, propylene glycol, and water in the pharmaceutical preparation.

17. The teaching of Deluca et al ('DeLuca) is drawn to parenteral formulations and useful carrier vehicles thereof. On page 175, Section B, it is noted that most parenteral products are aqueous solutions. However, inclusion of water may have to be limited if the active compound is susceptible to chemical degradation (i.e. hydrolysis, racemization, etc.). It is stated that for non-polar substances possessing limited solubility in water, it is necessary to use co-solvents such as ethanol and propylene glycol. Although DeLuca does not specifically teach adding the ingredients together in the amounts claimed. The amount of a specific ingredient in a composition is a result effective parameter that any person of ordinary skill in the art would desire to optimize. The instantly claimed percentages of said solvents, as described above, could readily be attained by routine experimentation and optimization.

18. Thus, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to combine the teachings of '508 and DeLuca because in doing so one would create a pharmaceutically active formulation suitable for safe administration to a patient. The instantly claimed compound are obvious as they are structural isomers of reference '508 and

one of ordinary skill in the art would be motivated to make such modifications with the expectation that the compounds and compositions thereof would possess identical pharmacological properties as those taught by the reference. Moreover, the use of water, ethanol, and/or propylene glycol as a carrier medium would be motivated by '508 statement that all pharmacologically acceptable carrier mediums can be sued to carry the drugs. This motivates one to look to the prior art of drug formulations where is found that solvents such as water, ethanol and propylene glycol are commonly used as a carrier medium. Furthermore, the specifically claimed percentages of said carrier does not qualify as patentable subject matter, as these values could found via routine experimentation and optimization. Therefore, it would have been obvious to a person of ordinary skill in the art to combine the teachings of '508 with that of DeLuca with a reasonable expectation of success.

Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kyle A. Purdy whose telephone number is 571-270-3504. The examiner can normally be reached from 9AM to 5PM.

20. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisors, Ardin Marschel and Cecilia Tsang, can be reached on 571-272-0718 or 571-272-0562, respectively. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

21. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Kyle A. Purdy/
Examiner, Art Unit 4173

Ardin H. Marschel 11/2/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER